DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Kathleen M. Sanzo, Esquire
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1800 M Street, N.W.
Washington, D.C. 20036-5869

MAY 24 2001

Re: Docket No. 78N-0038
Comment Nos. PSA2, SUP32

Dear Ms. Sanzo:

This responds to your Petition for Stay of Action (Petition) dated November 10, 2000 and your supplement to that Petition dated January 5, 2001 in which you, on behalf of Playtex Products, Inc. (Playtex), express your opposition to exempting products that contain sunscreens from the labeling requirements currently set forth in 21 C.F.R. §§ 201.66 and 352.52. Specifically, your Petition and its supplement request that the Food and Drug Administration (FDA): (1) stay the effective date of any pending, tentative, or final decision to exempt make-up, moisturizers, or other products used on the face that include sunscreen ingredients from the agency's over-the-counter (OTC) and sunscreen drug labeling regulations as set forth in 21 C.F.R. §§ 201.66 and 352.52; and (2) stay the effective date of any labeling requirements as they apply to any product that includes sunscreen ingredients pending resolution of the exemption issues.

I. Criteria for Granting a Petition for an Administrative Stay of Action

21 C.F.R. § 10.35 states:

> (a) The Commissioner may at any time stay or extend the effective date of an action pending or following a decision on any matter.
>
> (b) An interested person may request the Commissioner to stay the effective date of any administrative action. * * *
>
> (e) * * * The Commissioner may grant a stay in any proceeding if it is in the public interest and in the interest of justice. The Commissioner shall grant a stay in any proceeding if all of the following apply:
>
> (1) The petitioner will otherwise suffer irreparable injury.
> (2) The petitioner's case is not frivolous and is being pursued in good faith.
> (3) The petitioner has demonstrated sound public policy grounds supporting the stay.
> (4) The delay resulting from the stay is not outweighed by public health or other public interests.

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The granting of a stay is discretionary if the Commissioner finds that it is in the public interest and in the interest of justice. For a non-discretionary stay to be granted, however, all four criteria set forth above must be met.

FDA has carefully considered your Petition under the criteria set forth in § 10.35 and is denying your requests for the reasons set forth below.

II. The first request: To stay the effective date of any pending, tentative, or final decision to exempt make-up, moisturizers, or other sunscreen products used on the face ("sunscreen face products") from the OTC sunscreen and drug labeling requirements.

In your Petition (p. 1), you frame the scope of your first request for relief in terms of an "exemption request" submitted by the Cosmetic, Toiletry, and Fragrance Association (CTFA) for combination sunscreen and cosmetic products used on the face, which you refer to as "sunscreen face products." Thereafter, you consistently use the term "sunscreen face products" to reference the products to which your Petition pertains. For purposes of this response, FDA assumes that the CTFA "exemption request" to which you refer is the request contained in the comment that CTFA submitted to Docket Number 78N-0038 on August 6, 2000. Accordingly, FDA does not read your Petition for Stay to extend to the existing exemptions in 21 C.F.R. § 352.52(f) for sunscreen products that are labeled for use only on specific small areas of the face. Indeed, your Petition itself states (p. 8) that the limited exemption granted for sunscreen products in section 352.52(f) is inapplicable to "sunscreen face products." FDA therefore interprets the scope of the first request in your Petition as related only to the issue of a labeling exemption for sunscreen products for use on the face, neck, or hands.

With respect to your first request, FDA cannot grant the relief you seek at this time because there is no "decision" or "effective date" upon which can be stayed under sections 10.35(a) or (b). The agency has not made any decision to exempt make-up, moisturizers, or other such products from FDA's drug labeling regulations in the manner you describe. Your Petition does not cite any effective date for such a decision, nor does it identify any action (administrative or otherwise) that FDA has initiated in furtherance of the CTFA exemption request. Because FDA has not made the decision you seek to stay, your first request will not be granted under section 10.35.

III. The second request: To stay the effective date of any labeling requirements as they apply to any sunscreen product pending resolution of the aforementioned exemption issue.

Your second request seeks to stay the implementation dates of two regulations, 21 C.F.R. §§ 201.66 and 352.52. Section 352.52 is part of the final monograph for OTC sunscreen drug products that FDA published as a final rule in the Federal Register on May 21, 1999 (64 FR 27666). Section 201.66, which is the new OTC drug labeling regulation, is the codification of a final rule FDA published in the Federal Register on March 17, 1999 (64 FR 13254). Section 201.66 imposes general labeling requirements on all OTC drug products and applies to all OTC sunscreens products unless a provision of section 352.52 provides otherwise.

1. FDA denies your request because you have not demonstrated that you will otherwise suffer irreparable injury.

FDA declines to grant your second request for relief because, under 21 C.F.R. § 10.35(e)(1), you have not demonstrated that Playtex will otherwise suffer irreparable injury.

Your Petition suggests Playtex will suffer irreparable injury if the rules are not stayed because granting a labeling exemption for sunscreen face products "will confuse consumers" and convey to them the idea that proper use of sunscreen products intended for facial application "is not essential to health." While these observations certainly argue against granting an exemption for sunscreen face products, your Petition does not adequately demonstrate the existence of an irreparable injury to Playtex.

You also suggest in your supplement that granting a labeling exemption for sunscreen face products may disadvantage Playtex competitively as a result of increased labeling costs and a perception that sunscreen products that lack OTC drug labeling may seem more attractive to consumers. You state that such an injury will be ongoing and irreparable as long as a labeling disparity exists between exempted sunscreen face product and other similar sunscreen products. Since the agency has not made any decision to exempt sunscreen face products from either §§ 201.66 or 352.52, however, the injury that you allege is purely speculative. Again, your Petition argues against the merits of granting a labeling exemption, but it does not adequately show how Playtex will be irreparably injured if FDA refuses to stay regulations that will not otherwise be effective until December 31, 2002.

2. FDA denies your request because you have not demonstrated sound public policy grounds supporting the stay.

FDA declines your second request for relief because, under 21 C.F.R. § 10.35(e)(3), you have not demonstrated sound public policy grounds supporting the stay.

21 C.F.R. § 352.52 applies to all sunscreen drug products, not just sunscreen face products. The use of properly formulated and labeled sunscreens is important to the public health, especially given the incidence of sun-related skin cancers in the United States.

On November 21, 1997, Congress enacted the Food and Drug Administration Modernization Act (FDAMA). Section 129 of FDAMA directed FDA to issue regulations for OTC sunscreen products for the prevention or treatment of sunburn. The agency finalized the UVB portion of its pending tentative final monograph for sunscreens on May 21, 1999 to meet the FDAMA deadline. The final monograph includes 16 active ingredients, requires labeling for sunscreen products, a standardized test for measuring SPF values, and standard methods for measuring the water resistant properties of the products. The agency set an initial effective date of May 21, 2001, but extended that date until December 31, 2002 so the agency could continue its work on a

"comprehensive" sunscreen final monograph that will address formulation, labeling, and testing for both UVB and UVA radiation protection.

FDA promulgated the final monograph for OTC sunscreen drug products because Congress and the agency recognized the importance of standardizing these important drugs as quickly as practicable. The agency has already extended the effective date of the rule until December 31, 2002 and does not believe that, as a matter of public policy, your concerns regarding an exemption that has not even been granted justifies a further delay. The agency wants all OTC drug products, including sunscreen products, to have the final monograph labeling information (§ 352.52) in the new OTC drug labeling format (§ 201.66) at the earliest possible date. Furthermore, sunscreen face products are only a fraction of the total sunscreen products covered by the monograph, and FDA considers it inappropriate to further delay the rule with respect to all sunscreen drug products pending resolution of an issue that affects only a portion of the products covered by the rule.

Your Petition also requests a stay of applicable parts of § 201.66. The OTC drug products labeling rule sets forth important content and format requirements that apply to all OTC drug products, not just sunscreens. FDA developed the rule because it believes that providing consumers with important drug information in a prominent and easy to read format is essential for the safe and effective use of OTC drug products. See 64 FR 13267. FDA established standardized content and format labeling requirements to help consumers locate and read health and safety information and allow quick and effective product comparisons, thereby helping consumers select the most appropriate products.

The public health interests at stake in the labeling rule are therefore significant for all OTC drug products, including sunscreen products. See 62 FR 9024-9027. The standardized format and content requirements of the rule are intended to help consumers better read drug labeling and apply the information to the safe and effective use of OTC drug products. The rule also standardized important warning language to make it more concise and easier to understand. As you argue in your Petition, these many interests are important for the safe and effective use of all OTC drug products, including sunscreens.

The effective date for the labeling rule was May 16, 1999. See 64 FR 18571 (April 15, 1999 correction notice). However, the actual implementation dates for the rule vary among OTC drug products. See 64 FR 13273. These dates were originally set forth in the final rule, but FDA recently extended them to give industry more time to comply with the rule's requirements. See 64 FR 38191. In the case of products marketed under the final monograph for OTC sunscreen drug products, compliance with § 201.66 is not required until December 31, 2002. See 65 FR 38191 and 65 FR 36319.

Your Petition does not adequately explain why, as a matter of public policy, FDA should further delay rules that are not effective until December 31, 2002. Even assuming for the sake of argument that FDA were to propose a face product exemption later this year, the entire sunscreen

industry would still have 12 to 15 months to comply with the rule or to seek judicial review. Your Petition does not articulate sufficient public policy grounds to justify a stay of the agency's important OTC drug labeling initiative while the agency considers what exemptions, if any, should apply to sunscreen face products.

Your Petition presents policy arguments regarding the merits of the exemption itself, and the agency will give them full weight and consideration. However, the observations you make about the merits of an exemption do not justify the specific relief you request. The agency has not made any decision to exempt sunscreen face products in the manner you describe, and FDA believes that there are no compelling public policy grounds to stay two important public health rules that are not yet effective and do not themselves include the exemption to which you object.

3. FDA denies your request because the delay that would result from your request is outweighed by the public interest.

FDA declines to grant your second request for relief because, under 21 C.F.R. § 10.35(e)(4), the relief you seek is outweighed by the public interest.

For the reasons stated above, the agency has determined that any further delay in the effective date of the rules based on the concerns cited in your Petition is not in the public interest. FDA has also decided that the specific relief you request is outweighed by the need to ensure that safe, effective, standardized, and properly labeled sunscreen products are readily available to consumers as soon as possible.

As noted, the public health interests at stake in these rules are compelling. FDA developed both the OTC drug labeling rule and the sunscreen final monograph as part of a continuing effort to help consumers better understand and use drug products that contain sunscreens. FDA has considered your Petition carefully but sees no reason to delay the important public interests served by these rules since the agency has not even made a decision to grant the exemption to which you object. The rules as codified do not permit a labeling exemption for "sunscreen face products." The injury you allege in your Petition is therefore entirely speculative, and your desire to stay the rules while FDA considers what labeling exemptions, if any, should be developed is outweighed by the strong public interest in having these rules and their protections become effective as soon as possible. This is especially true since the effective date that you seek to stay has already been pushed back to December 31, 2002.

Finally, with respect to both your requests for relief, the agency has concluded that the criteria set forth in § 10.35 are not satisfied because the exemption issue you raise will be addressed in a future rulemaking. As you know, the agency re-opened the administrative record for the sunscreen final monograph when it extended the effective date of the rule on June 8, 2000 (65 FR 36319). FDA is currently evaluating data and information regarding OTC sunscreen drug products and is considering the comments made in response to that Federal Register notice. As

noted, it is clear that your Petition to Stay is, at least in part, a reply to the request for exemption made by CTFA.

FDA intends to address the exemption issues that you and CTFA raised in a proposed rule for a comprehensive final monograph for OTC sunscreen drug products in a future issue of the Federal Register. Since FDA will formally address the exemption issue through a public administrative process, your present concern regarding the need for a stay is obviated. All parties will have the opportunity to consider and respond to that future Federal Register document at the same time. If any exemptions for "sunscreen face products" were to be included in the final monograph, they would result from notice and comment rulemaking and would apply to all parties at the same time.

IV. CONCLUSION

FDA denies your requests that the agency (1) stay the effective date of any pending, tentative, or final decision to exempt "sunscreen face products" and (2) stay the effective date of any labeling requirements as they apply to any product that includes sunscreen ingredients pending resolution of the exemption issues.

The agency has determined that it is not in the public interest or in the interests of justice to grant such stays. The agency has also concluded that the possible delay resulting from the stay is outweighed by the public health, that your Petition does not demonstrate sound public policy grounds in support of the relief that you request, and that your Petition does not demonstrate that Playtex will suffer irreparable injury as a result of this denial.

If you have any questions regarding this petition denial, please refer to the docket and comment numbers above and submit all inquiries in triplicate to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Sincerely yours,

Dennis E. Baker
Associate Commissioner
for Regulatory Affairs